

the health and safety of its participants. This determination may result from the identification of deficiencies that CMS or the State administering agency determines cannot be corrected.

(d) *Termination of agreement by PACE organization.* A PACE organization may terminate an agreement after timely notice to CMS, the State administering agency, and participants, as follows:

(1) To CMS and the State administering agency, 90 days before termination.

(2) To participants, 60 days before termination.

§ 460.52 Transitional care during termination.

(a) The PACE organization must develop a detailed written plan for phase-down in the event of termination, which describes how the organization plans to take the following actions:

(1) Inform participants, the community, CMS and the State administering agency in writing about termination and transition procedures.

(2) Assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits.

(3) Transition participants' care to other providers.

(4) Terminate marketing and enrollment activities.

(b) An entity whose PACE program agreement is in the process of being terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the participant's medical records available to new providers.

§ 460.54 Termination procedures.

(a) Except as provided in paragraph (b) of this section, if CMS terminates an agreement with a PACE organization, it furnishes the PACE organization with the following:

(1) A reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of CMS's determination that cause exists for termination.

(2) Reasonable notice and opportunity for hearing (including the right

to appeal an initial determination) before terminating the agreement.

(b) CMS may terminate an agreement without invoking the procedures described in paragraph (a) of this section if CMS determines that a delay in termination, resulting from compliance with these procedures before termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

Subpart E—PACE Administrative Requirements

§ 460.60 PACE organizational structure.

(a) A PACE organization must be, or be a distinct part of, one of the following:

(1) An entity of city, county, State, or Tribal government.

(2) A private not-for-profit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986. The entity may be a corporation, a subsidiary of a larger corporation, or a department of a corporation.

(b) *Program director.* The organization must employ a program director who is responsible for oversight and administration of the entity.

(c) *Medical director.* The organization must employ a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality assessment and performance improvement program.

(d) *Organizational chart.* (1) The PACE organization must have a current organizational chart showing officials in the PACE organization and relationships to any other organizational entities.

(2) The chart for a corporate entity must indicate the PACE organization's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities.

(3) A PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 60 days before the change takes effect.

(4) Changes in organizational structure must be approved in advance by

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CMS and the State administering agency.

(5) Changes in organizational structure approved by CMS and the State administering agency must be forwarded to the consumer advisory committee described in § 460.62(c) of this part for dissemination to participants as appropriate.

EFFECTIVE DATE NOTE: At 67 FR 61505, Oct. 1, 2002, in § 460.60, paragraphs (b) and (c) were revised, effective Oct. 31, 2002. For the convenience of the user, the revised text is set forth as follows:

§ 460.60 PACE organizational structure.

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(b) *Program director.* The organization must employ, or contract with in accordance with § 460.70, a program director who is responsible for oversight and administration of the entity.

(c) *Medical director.* The organization must employ, or contract with in accordance with § 460.70, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality assessment and performance improvement program.

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§ 460.62 Governing body.

(a) *Governing body.* A PACE organization must be operating under the control of an identifiable governing body (for example, a board of directors) or a designated person functioning as a governing body with full legal authority and responsibility for the following:

(1) Governance and operation of the organization.

(2) Development of policies consistent with the mission.

(3) Management and provision of all services, including the management of contractors.

(4) Establishment of personnel policies that address adequate notice of termination by employees or contractors with direct patient care responsibilities.

(5) Fiscal operations.

(6) Development of policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of participants.

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(7) Quality assessment and performance improvement program.

(b) *Community representation.* A PACE organization must ensure community representation on issues related to participant care. This may be achieved by having a community representative on the governing body.

(c) *Consumer advisory committee.* A PACE organization must establish a consumer advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee.

§ 460.64 Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, each member of the staff (employee or contractor) of the PACE organization must meet the following conditions:

(1) Be legally authorized (currently licensed or, if applicable, certified or registered) to practice in the State in which he or she performs the function or actions.

(2) Only act within the scope of his or her authority to practice.

(b) *Federally-defined qualifications for physician.* (1) A physician must meet the qualifications and conditions in § 410.20 of this chapter.

(2) A primary care physician must have a minimum of 1 year's experience working with a frail or elderly population.

(c) *Qualifications when no State licensing laws, State certification, or registration requirements exist.* If there are no State licensing laws, State certification, or registration applicable to the profession, the following requirements must be met:

(1) *Registered nurse.* A registered nurse must meet the following requirements:

(i) Be a graduate of a school of professional nursing.

(ii) Have a minimum of 1 year's experience working with a frail or elderly population.

(2) *Social worker.* A social worker must meet the following requirements: